Safety Guide 100

DESIGN GUIDE FOR PACKAGING AND OFFSITE TRANSPORTATION OF NUCLEAR COMPONENTS, SPECIAL ASSEMBLIES, AND RADIOACTIVE MATERIALS ASSOCIATED WITH TILE NUCLEAR EXPLOSIVES AND WEAPONS SAFETY PROGRAM

CHAPTER 9.0

QUALITY ASSURANCE

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FIGURES

ACRONYMS

ASME	American Society of Mechanical Engineers
CFR	Code of Federal Regulations
DOE	Department of Energy
DOE-AL	Department of Energy, Albuquerque Operations Office
DOT	Department of Transportation
IAEA	International Atomic Energy Agency
ISO	International Standards Organization
M&TE	Measurement and Test Equipment
NCR	Non Conformance Report
NRC	Nuclear Regulation Commission
QA	Quality Assurance
QAPD	Quality Assurance Program Description
SARP	Safety Analysis Report for Packaging
SNM	Special Nuclear Material

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9.0 QUALITY ASSURANCE

9.1 INTRODUCTION

9.1.1Purpose

The purpose of this Design Guide chapter is to assist packaging owners and users in developing and implementing an effective quality assurance (QA) program for packaging of nuclear components, special assemblies and radioactive material in support of the Department of Energy (DOE) nuclear weapons program. This design safety guide provides direction for the establishment and implementation of a QA program that will meet the applicable standards and requirements necessary for packaging certification (designing, developing and producing) and use of packaging by the DOE-Albuquerque Operations Office (DOE-AL). This design safety provides direction and guidance for integration and graded application for nuclear weapons packaging program activities without attempting to replace standards and requirements.

This Design Guide is one of a series of safety guides intended to provide direction and guidance for the sequential steps or phases of design, testing, fabrication, inspection, acceptance, use, and maintenance of weapons packaging. This guide is intended to apply to the performance of these steps in the process to the extent that the steps impact or affect packaging quality.

The following sections of this guide describe acceptable methods for preparation of a packaging QA program and emphasize the unique aspects that need to be included so that quality is achieved and assured.

9.1.2 Scope

This guide addresses the application of QA activities to packaging for nuclear components, special assemblies and radioactive material. This guide is limited to packaging certified by DOE-AL. However, the principles presented may be useful for any packaging QA program for nuclear materials.

This guide applies to package "owners" who design, develop, and produce packaging and who are responsible for the design, procurement, manufacture and fabrication, assembly, test, acceptance for use, and control of configuration. This guide also applies to package "users" who pack and unpack, handle, clean and decontaminate, refurbish, maintain, and repair. A "packaging owner" may or may not be the "user" of its own packaging.

While not a guide for a QA program used for preparation of a Safety Analysis Report for Packaging (SARP), the QA program description prepared using this guide should, as a minimum, be consistent with the one described in the SARP.

9.1.3 Objectives

The objectives of this Design Guide are to provide acceptable methods, direction, and terminology so that future QA program activities are built on an acceptable common and consistent basis of understanding across facility and organizational interfaces.

Consequently, this Design Guide provides acceptable methods for identification of applicable standards, requirements, and the subsequent documentation of the acceptable practices and methods that respond to and incorporate these requirements.

It is recognized that a number of DOE contractor facilities and organizations are or will be involved in future weapons packaging processes and packaging activities governed by this safety guide. Many, if not all, of these organizations currently have implemented QA programs for package design, development, and use. These programs may include policies, procedures, and practices that effectively respond to requirements and both achieve and assure the quality of packaging activities. Therefore, an objective of this Design Guide is to provide and incorporate methods that build on and use to the extent practical any of the currently acceptable QA practices that are in place within these organizations.

9.2 REQUIREMENTS

The DOE Packaging Program is based on a number of quality and technical assurance codes and standards, in addition to the applicable DOE directives and standards. There are also packaging requirements from other federal agencies such as the U. S. Nuclear Regulatory Commission (NRC) and the Department of Transportation (DOT). The NRC and DOT have requirements for packaging design, development, and use, and cover transportation of the packaging once it leaves the packaging owner's facility and is transported to the User's facility. DOE Order 5700.6C, *Quality Assurance*,[1] establishes the QA requirements for all DOE elements and their contractors. This order specifies the QA requirements to ensure that risks and environmental impacts are minimized and that safety, reliability, and performance are maximized through the application of effective management contracts commensurate with the risks raised by each packaging program. Weapons components and/or special nuclear material (SNM) are covered under other relevant codes and standards when packaged for off-site transportation to a User's facility.

Since the regulations and requirements for various types of packaging are so complex, several codes and standards apply. (See Fig. 9.1) For example, requirements for packaging are identified in

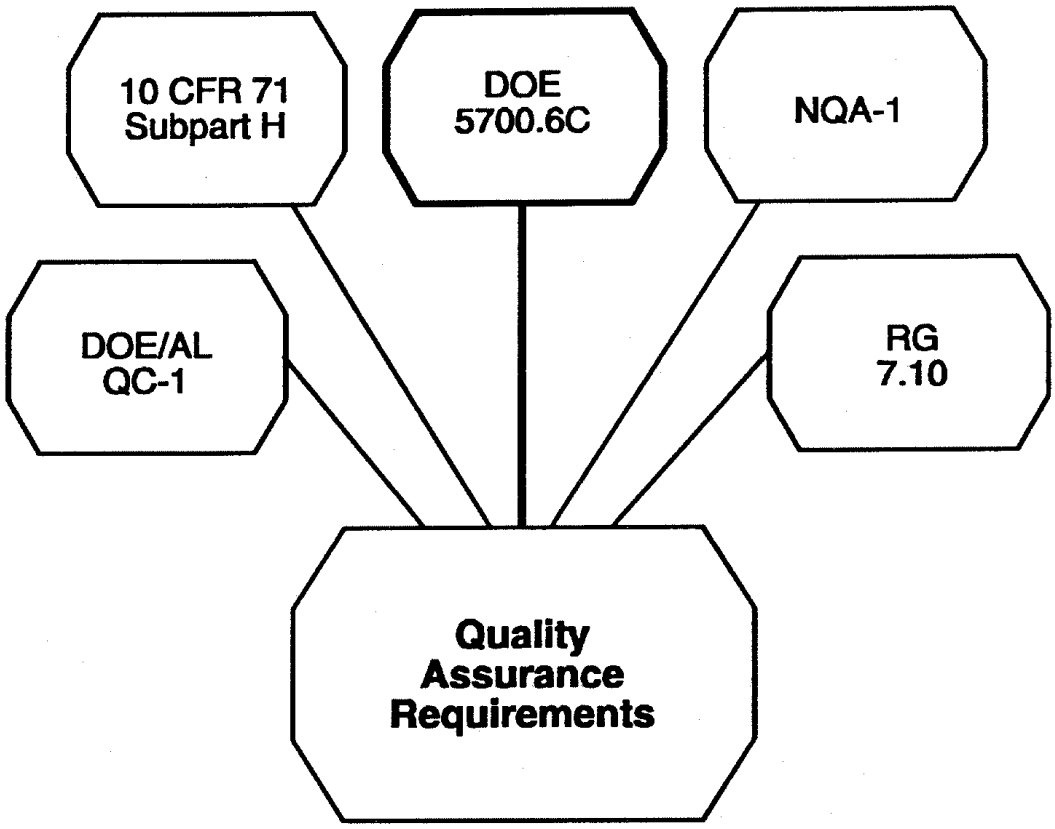

Fig. 9.1. Quality Assurance requirements.

49 CFR 171-179,[2] and 10 CFR Part 7l.[3] Following is a discussion of the pertinent QA and other requirements applicable to DOE packaging for the transport of weapons components and SNM.

9.2.1 Quality Assurance Requirements

The requirements which are to serve as the foundation for a packaging QA program are specified in DOE Order 5700.6C, which is discussed below. It is recognized that packaging packaging owners and users may be using other acceptable QA requirements documents as their current requirements foundation. The integration and use of acceptable packaging QA policies, procedures, and practices are discussed in Sect. 3.5.

9.2.1.1 DOE Order 5700.6C, *Quality Assurance*

This DOE Order establishes QA requirements for work associated with the design, construction, fabrication, operations, maintenance, decommissioning, and decontamination of facilities and equipment used to produce weapons, with appropriate attention given to the weapons component and production facility interfaces. Although the specific language in DOE 5700.6C is directed toward the broad spectrum of work performed by DOE and its contractors, these basic requirements are applied to other types of operations such as packaging. Appendix A[4] is a simplified list of the QA principles embodied in DOE Order 5700.6C. However, when applying this order to a program, one must work from the order and not the Appendix A listing.

9.2.1.2 10 CFR Part 71, Subpart H, "Quality Assurance"

Subpart H establishes packaging requirements for the transport of licensed material. These requirements cover design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components important to safety. Appendix B[5] is a simplified list of the QA principles enclosed in 10 CFR Part 71. However, when applying this standard to a program, one must work from the standard and not the Appendix B list.

9.2.1.3 ASME NQA-1, 1989 *Quality Assurance Requirements for Nuclear Facilities*[6]

This standard is the basic nuclear industry standard for establishing and implementing QA programs for the siting, design, construction, operations, and decommissioning of nuclear facilities.

The established QA program is intended to provide control over activities affecting quality consistent with their relative importance. This standard was referenced in DOE Order 5700.6B[7] and is still referenced in many other DOE Orders. Also, many DOE facilities and its contractors still have QA program descriptions based on the requirements of American Society of Mechanical Engineers (ASME) NQA-1.

9.2.1.4 DOE-AL QC-1,[8] *Quality Criteria* (Rev 6, 1992)

This criteria document contains QA requirements for the DOE production and design agencies responsible for procurement and/or production of weapons and weapons-related material and software. These requirements ensure the integrity of weapons components.

9.2.1.5 USNRC Regulatory Guide 7.10, *Establishing Quality Assurance Programs for Packaging Used in the Transportation of Radioactive Material* (Rev. June 1, 1986)[9]

This document provides guidance to organizations which are subject to the QA requirements of 10 CFR Part 71. It addresses the essential elements needed to develop, establish, and maintain a QA program for packages transporting radioactive materials which are acceptable to the NRC.

9.2.2 Other DOE Orders Relative to Packaging

The following documents contain technical requirements and some necessary QA requirements (see Fig. 9.2).

9.2.2.1 DOE Order 1540.1, *Materials Transportation and Traffic Management*[10]

This Order establishes policies and procedures for the management of materials transportation activities, including traffic management, for other than intrabuilding and intrasite transfers.

9.2.2.2 DOE Order 1540.2, *Hazardous Material Packaging for Transport - Administrative Procedures*[11]

This Order establishes administrative procedures for the certification and use of packaging for radioactive and other hazardous materials. (Refs.: 10 CFR Part 71, *Packaging of Radioactive Material for Transport and Transportation of Radioactive Materials Under Certain Conditions;*[12] 10 CFR 49 Parts 171-179, *Hazardous Material Regulations).*

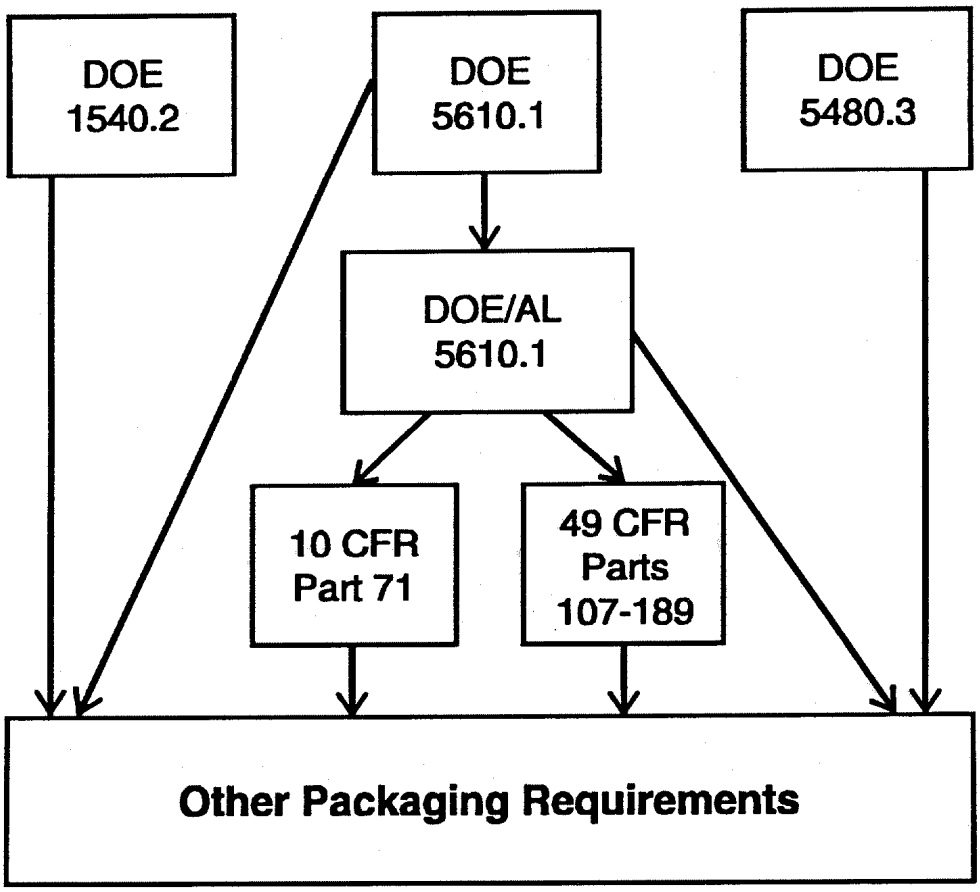

Fig. 9.2. Other packaging requirements.

9.2.2.3 DOE Order 5610.1, *Packaging and Transporting of Nuclear Components and Special Assemblies*[13]

This Order establishes criteria for nuclear components and special assemblies to be packaged and transported in accordance with applicable regulations. DOE Order 5610.12 (draft) will be replacing this order when issued in final approved form.

9.2.2.4 DOE Order AL SD 5610.1, *Packaging and Off-Site Transportation of Components and Special Assemblies Associated with the Nuclear Weapons Program*[14]

This draft Order supplements DOE-AL established policy and requirements, and it assigns responsibilities for the safe off-site transportation of components and special assemblies in support of the nuclear weapons program and in custody of DOE.

9.2.2.5 DOE Order 5480.3, *Safety Requirements for the Packaging and Transportation of Hazardous Materials, Hazardous Substances, and Hazardous Wastes* [15]

This Order establishes requirements for the packaging and transportation of hazardous materials, hazardous substances and hazardous wastes (radioactive materials).

9.2.3 International Requirements

It is expected that DOE packaging will be used to transport weapons components and/or special assemblies outside of the United States to or from foreign countries and on international waters. In

addition to the applicable DOE Orders, DOT Regulations, and NRC requirements, there are several international regulations which establish criteria for compliance with identified transport regulations.

There are international standards which address nuclear QA requirements. Two of the more widely recognized standards are the International Atomic Energy Agency's (IAEA's) Safety Series No. 50-C-QA, Code on the Safety of Nuclear Power Plants, QA,[16] and the International Standards Organization (ISO)-9001, Model for QA in Design/Development, Production, Installation, and Servicing.[17] These standards identify somewhat different criteria or requirements for a QA program. If the packaging owner finds it necessary to incorporate an international standard into the existing QA program description, the packaging owner should 1) identify any areas where additional treatment of a given requirement is necessary, and 2) incorporate that detail into the document text or use a matrix to reflect the correlation of requirements and implementing procedures and instructions.

9.2.4 DOE Transportation Management Program Requirements

Figure 9.3 shows the flowdown of requirements for QA program activities applicable to the overall DOE Transportation Management Program. This figure identifies the requirements imposed by DOE and other organizations. The requirements for packaging are included. Following are discussions of the various requirements necessary for a working, viable QA program for packaging.

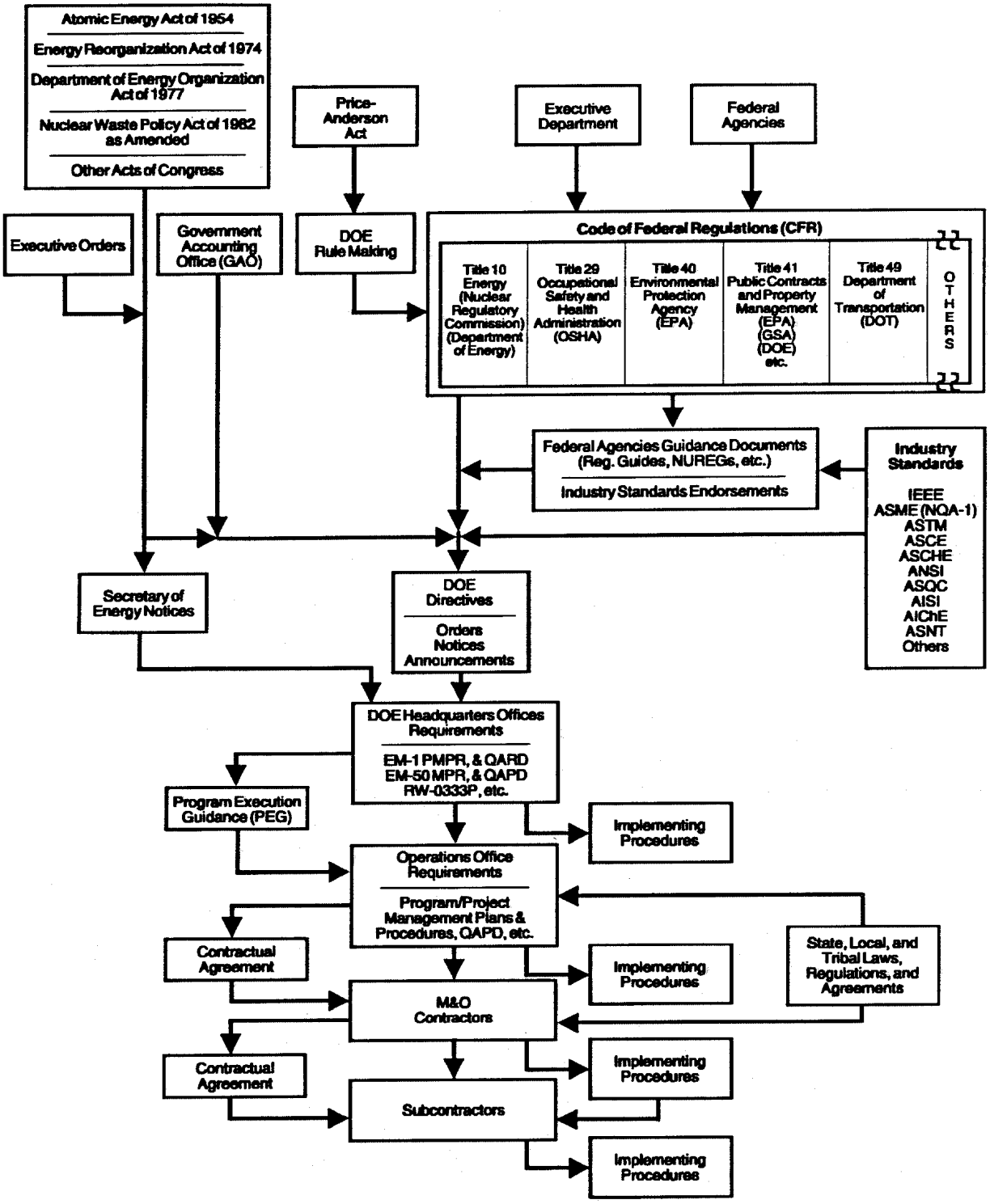

Fig. 9.3. Flowdown and interrelation of requirements for DOE transportation management program.

9.3 QUALITY ASSURANCE PROGRAM

9.3.1 Concepts

The purpose of a QA program is to provide confidence. This confidence applies at several different levels and is perceived and evaluated differently by different people. The fundamental purpose of the QA program is to provide confidence to all interested parties, through all points in the work process, that quality has been achieved and that it has been achieved in the correct manner.

In a technical, highly regulated activity such as the packaging process for nuclear materials, each responsible organization has two main factors to consider: achieving quality and providing confidence (or assuring quality). Both activities take place in the context of the basic model shown in Fig. 9.4.

Each organization has a basic set of work activities for achieving its mission. These work activities are performed along with a set of management systems that are established to provide guidance and control of individual work activities. Management systems must be established not only to facilitate the correct and efficient accomplishment of work, but also ensure that the organization's work requirements are met. There are usually three types of requirements:

1. Requirements specified by the customer
2. Requirements and standards adopted internally by the organization
3. Requirements imposed by outside regulatory agencies

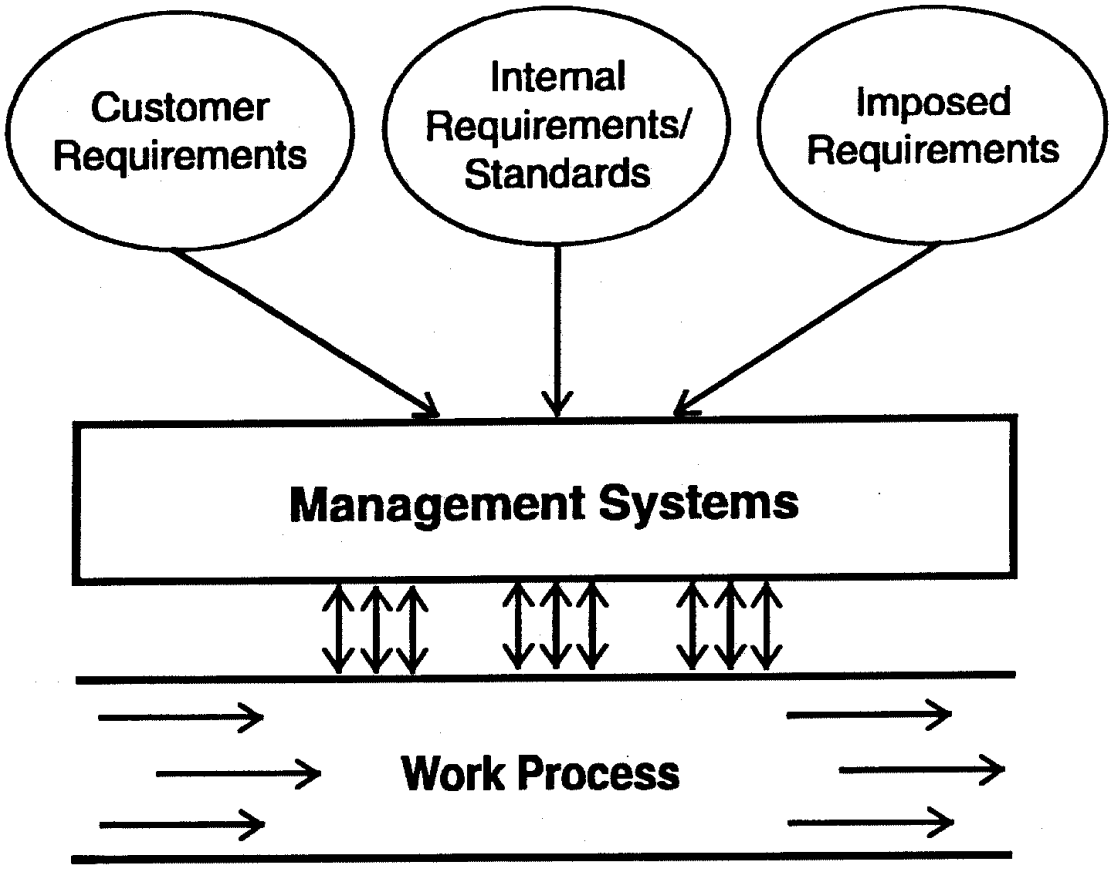

Fig. 9.4. Packaging process for nuclear materials.

Achieving quality in a technical, highly regulated environment requires that the individual work activities carried out by the organization be performed in a manner that meets all requirements. If the organization meets the requirements of the regulators, satisfies its own internal standards, and satisfies the customer by meeting needs and expectations, then that organization has achieved quality.

QA actions must be established and implemented so that they become an integral part of the work process. The work process includes the generation of objective evidence which provides confidence that quality has been achieved. QA actions should not be an extraneous set of actions to be taken once the work is completed. The key to successful implementation of QA actions is their integration with an organization's management practices and work process. The QA program provides a structure within which both management practices and work processes can be integrated.

9.3.2 Participants

The packaging owner is the organization applying for and being issued the Off-Site Transportation Certificate. The packaging owner designs, develops, produces, and accepts the packaging for which certification is requested. The packaging owner can also be a packaging user that either ships or receives. Packaging users are the organizations that pack, unpack, and refurbish packaging. There are generally at least two packaging user organizations, one packaging user that packs and ships from one facility, and one packaging user that receives and unpacks at another facility. The organization that refurbishes the packaging is also a packaging user and may be separate or different from those that pack or unpack.

Subcontractors and suppliers support packaging owners and users. Subcontractors and suppliers may be organizations that design, test, procure, fabricate, assemble, track, control configuration, etc.

For packaging users, subcontractors or suppliers may calibrate measurement and test equipment, refurbish, perform health physics checks, etc.

Only those activities that apply to the packaging program should be considered for delegation or implementation. Integrating all participants fulfills the overall program requirements. A systematic method should be employed whereby activities are identified and structured for implementation or delegation. The technique of dividing and further subdividing the work for delegation may progress through many tiers of participants.

9.3.3 Planning

Planning the application of the QA program to a new packaging design initiative includes several steps. The first step is to analyze the work scope to which the QA program will apply. This should include a breakdown of the work into its elements (and subelements where appropriate) and a determination of how and where (internally or externally) the work will be performed. The sequence of performance and the interrelationship among activities should be identified wherever possible, and the significant steps should be scheduled.

9.3.3.1 Planning considerations

The contract, purchase order or other work authorization document defining the scope of the work should be reviewed to clearly identify the following items:

1. Packaging initiative to be performed to attain quality objectives
2. Quality affecting activities to be used to accomplish the work

3. QA programmatic activities to be applied to required quality affecting activities
4. The pertinent requirements for QA work-oriented activities.

Any task to be performed in which QA objectives are to be met should be analyzed to clearly identify the following needs:

1. Special controls, processes, equipment, or facilities
2. Special skills or for indoctrination and training of personnel
3. Verification of quality attainment by inspection and testing
4. Procedures, instructions, and drawings.

The internal organization should determine the extent to which it should establish and implement the assigned scope for QA activities or delegate to another organization. Accomplishing a meaningful analysis of the work scope requires an understanding of the packaging process. For example, the overall packaging process can be broken down into the following broad elements: designing, developing, producing, accepting, and using.

9.3.3.2 Planning the overall packaging process

To plan the packaging process, one must completely understand the work processes that constitute the packaging process. Once the high-level definition is complete, more detailed analyses can begin. The designing element initiates the work process by addressing the structural, thermal, and shielding functions, along with containment protection to ensure that criticality will not occur during packing, handling, shipping, and design basis accident conditions. The packaging design must incorporate these functions and requirements to ensure the containment and protection of the part or assembly being

shipped. Practical design requirements include ease of loading and unloading, leak testing, and ability to economically control contamination and decontamination. The selection of appropriate materials and fabrication must also be considered.

Once designing is complete, development may be initiated. Developing includes fabrication of prototypes. The prototype quality must be consistent with the production quality, since the prototypes are to validate the practicality of production fabrication and to provide packaging for the performance testing per the required accident conditions. Developing also includes actual testing and post-test evaluation. The safety analysis begun during the design stage continues during developing, with the issued-for-comment SARP is the end result.

Producing includes preparing the procurement technical specification package for the supplier, along with the procurement quality specification, the supplier evaluation, and when specified, the first article evaluation. The packaging is then manufactured.

Accepting the manufactured packaging involves monitoring the supplier's manufacturing operations, dispositioning nonconforming materials and parts identified by the supplier, and performing acceptance inspection and testing. The final acceptance process should be a readiness review to ensure the packaging's overall acceptance. The review should include validation of design, development, and production. Readiness reviews may be conducted at the completion of each of the above phases.

Using the packaging involves several different work processes, including packing, unpacking, and refurbishing. These processes can be subdivided further. For example, packing may typically include a preloading inspection, the actual packing activity, a post-load inspection, a leak test, and a health physics survey. Unpacking has a similar breakdown. In this manner, the overall packaging process

should be completely broken down into its constituent parts. Then each part can be examined and defined in terms of the following:

1. Inputs and outputs
2. Basic events and their relationships to one another (flow)
3. Interface points with other parts of the process
4. Key organizations or positions involved
5. Key points requiring controls

A process must be understood before it can be controlled. This will result in a detailed understanding of the work process needed for decisions. It is important to be aware that several facilities may be involved with the use of packaging. The packer is probably located at a different facility from the unpacker and may have a totally different QA program. This consideration is discussed in Sect. 9.5.

In addition to the requirements of the customer and the organization's internal requirements, attention should be given to identifying the imposed requirements that may pertain to the process. QA requirements are stated in a number of standards as discussed in Section 9.2. (Also see Fig. 9.5)

Many requirements found in the standards are identical or at least very similar. In analyzing the QA requirements, the QA standards or parts thereof that are applicable should be identified.

The packaging owner's organization may have, in addition, its own QA requirements. These requirements should be reviewed to identify and analyze any packaging owner's QA requirements not addressed in the QA standards. Packaging owner requirements and the organization's internal

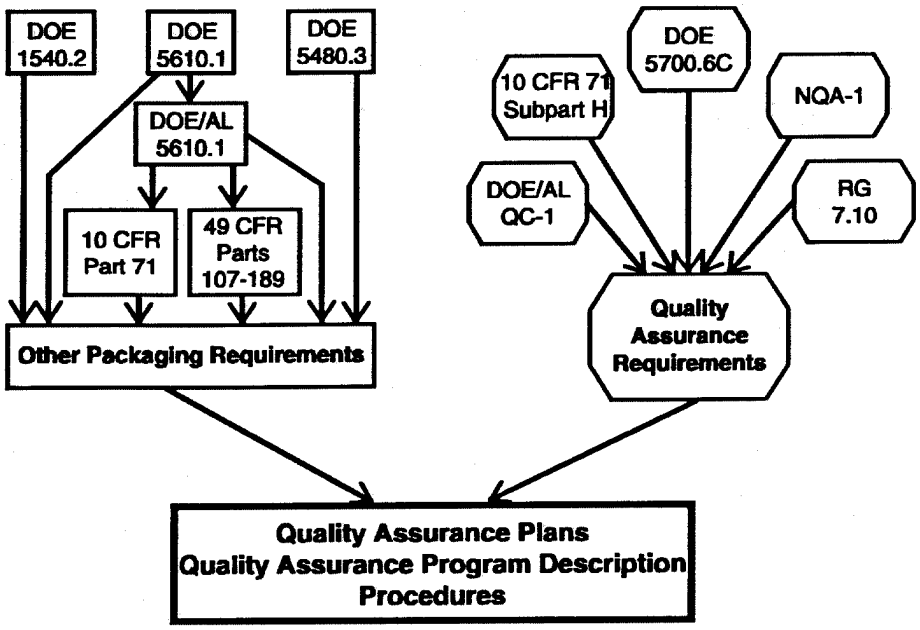

Fig. 9.5. Quality assurance program description procedures.

requirements must be specified and incorporated into the overall package that will determine the design of the organization's QA program.

Any requirements from various sources that could apply to packaging should be identified. Communicating with other organizations that perform similar work is a good way to validate the organization's requirements and identification process, and it may help in identifying omissions or other problems.

9.3.4 Personnel Selection, Indoctrination, Training, and Qualification

Personnel assigned to perform activities that affect quality receive appropriate indoctrination and training in accordance with ASME NQA-1, Supplement 2S-4 prior to performing the work.

9.3.4.1 Personnel selection

Personnel assigned to perform quality-affecting activities of the packaging Programs have the education, experience, and/or training commensurate with the functions and requirements associated with the work. Initial qualifications are verified as a result of DOE-mandated policies, which provide for the inclusion of qualification requirements in position descriptions.

The candidate's qualifications are evaluated against the requirements and are documented. Relevant education and experience are verified accordingly. Records on individuals generated by affected organization's training and qualification program are collected and maintained according to the Privacy Act of 1974.

9.3.4.2 Determination of indoctrination and training

Each organization reviews job functions or tasks involved in performing activities associated with the Packaging QA Program and determines any additional indoctrination and training required of the supporting staff.

Personnel assigned responsibility for performing Packaging QA Program activities are indoctrinated in the purpose, scope, and implementation of the QA program described in this chapter. This indoctrination includes the following:

- Applicable Standard Practice Procedures
- Applicable QA program elements as described in this Design Guide
- Job responsibilities and authority

9.3.4.3 Training and qualification

Classroom training is performed in accordance with documented lesson plans. Records of training are maintained. Personnel serving as lead auditors or auditors are qualified in accordance with ASME NQA-1, Supplement 2S-3 and Appendix 2A-3.

9.3.4.4 Proficiency evaluations

Supervisors evaluate, at least annually, the proficiency of personnel in performing their assigned duties. These evaluations determine if any additional education and/or training is needed for the individual to maintain the desired level of proficiency.

9.3.5 Other Packaging Considerations

In addition to this chapter, other chapters of the Safety Guide 100 present specific functional design guidance for the design and use of DOE packaging. These chapters address structural, material and fabrication, thermal, containment, shielding, criticality, operations, and maintenance and acceptance aspects of packaging. These chapters present specific functional guidance for the design and use of DOE packaging and provide the necessary quality achieving activities. These activities include the work carried out as part of the designers' efforts and they directly contribute to producing packaging which satisfies the needs and expectations of the clients. Through this basic set of activities, the designers focus their expertise on each packages needs and requirements. By completing each phase of the design work (i.e., structural aspects, thermal aspects, etc.), the designer subsequently accepts responsibility for certain QA activities such as documenting and controlling of design input, documenting and controlling the design process, planning and controlling the design analysis, verifying the adequacy of the design, controlling changes to the design, identifying and controlling the interfaces, and ensuring that the design is documented and recorded and that these records are then stored and maintained in accordance with approved procedures.

In conjunction with the independent overview by the respective management organization, the quality assuring activities provide the necessary overall controls to ensure that quality is achieved during the designing, developing, producing, certifying, and using phases of the packages.

9.3.6 Policies, Procedures, and Practices

9.3.6.1 Packaging quality assurance policies

A written QA policy statement should be prepared, signed, and issued by the senior persons in the packaging owner and user organizations. The policy statement is the first requirement in DOE Order 5700.6C, which defines a QA program as the overall program established by an organization to implement the requirements of this order. The program assigns responsibilities and authorities, defines policies and requirements and provides for the performance and assessment of work. The policy should:

1. Document the way work is performed.
2. Add the necessary controls that are necessary and achievable.
3. Evaluate the proposed program against accepted QA standards.

Each person in the organization involved in packaging activities should understand and be aware of this packaging policy. Failure to accept and implement this packaging policy could undermine and destroy the confidence being built into the program regarding assurances of form, fit, and function.

9.3.6.2 Packaging quality assurance procedures and written instructions

Written procedures, work plans, schedules, drawings, and working instructions or checklists needed to define the program-specific actions to be performed to execute the program should be identified and required when the activity results in a quality record or when the activity involves quantitative acceptance criteria. These preparations should be planned, scheduled, and accomplished in a timely manner.

Draft DOE Order 5480. PRO[18] provides additional guidance on when written procedures are required. The guidance includes special attention to infrequent performance, complex situations, high consequences of error, performance which depends on a large body of information, performance which depends on changing information, or high turnover of personnel on simple tasks.

The packaging QA program should be built on existing practices. Requirements and controls should be applied as necessary to achieve and ensure that regulations, requirements, and the customer's needs and expectations are met. The packaging QA programs for packaging owners and users should use existing procedures and written instructions when the required control is included in existing documents.

The QA program should be based on current practices. Most facilities have a "plant"-level QA program which contains many of the programmatic elements needed for the packaging QA program which should not be duplicated or replicated. The Packaging QA Program should incorporate existing controls by reference. Many existing QA elements should be fully adequate as they stand. These elements are qualification of auditors, record storage, measurement and test equipment (M&TE) control and calibration, personnel qualifications, authority to control further processing, processing allegations and differing opinions. Other elements such as Nonconformance Report (NCR) processing, corrective action, identification and processing of quality records, and control of procured items may need supplementing. For example, when there is a special need, a "plant" level procedure just for packaging can be used, just as "division" and "department" level procedures that contain needed controls should be incorporated into the Packaging QA Program by reference.

Instructional material for the individual performers should be in a single document or set of documents. If the QA activities are controlled by one document and the technical requirements are in

a separate document, the QA document will tend to be overlooked or may be ignored. The individual performer's written instructional material should be presented comprehensively, in a user friendly manner. It should not contain material irrelevant to the individual performers activities (see Fig. 9.6).

9.3.6.3 Packaging quality assurance practices

The existing organization is responsible for implementing QA activities. Standard policies and procedures available for meeting requirements and for achieving the desired results should also be evaluated. Any requirements not fully covered should be identified so that plans can be made for the necessary modification or additions.

Early in this analysis, specific responsibility assignments should be made for key positions in the organization. The organization should be staffed with the appropriate number of qualified personnel. Staffing plans should include provisions for selecting, training, and assigning adequate numbers of personnel, in conformity with the schedule for performing the work.

Resource planning should include an evaluation of the existing equipment and facilities and should identify any improvements needed. If additional equipment or facilities are required, provisions should be made for their acquisition. The need for any support services should also be determined and provided for.

Packaging controls should be applied using a graded process based on risk and programmatic importance. This selective application of packaging controls is intended such that the depth of detail required and the magnitude of resources expended for a particular technical control or management control is commensurate with the element's importance relative to the risk involved.

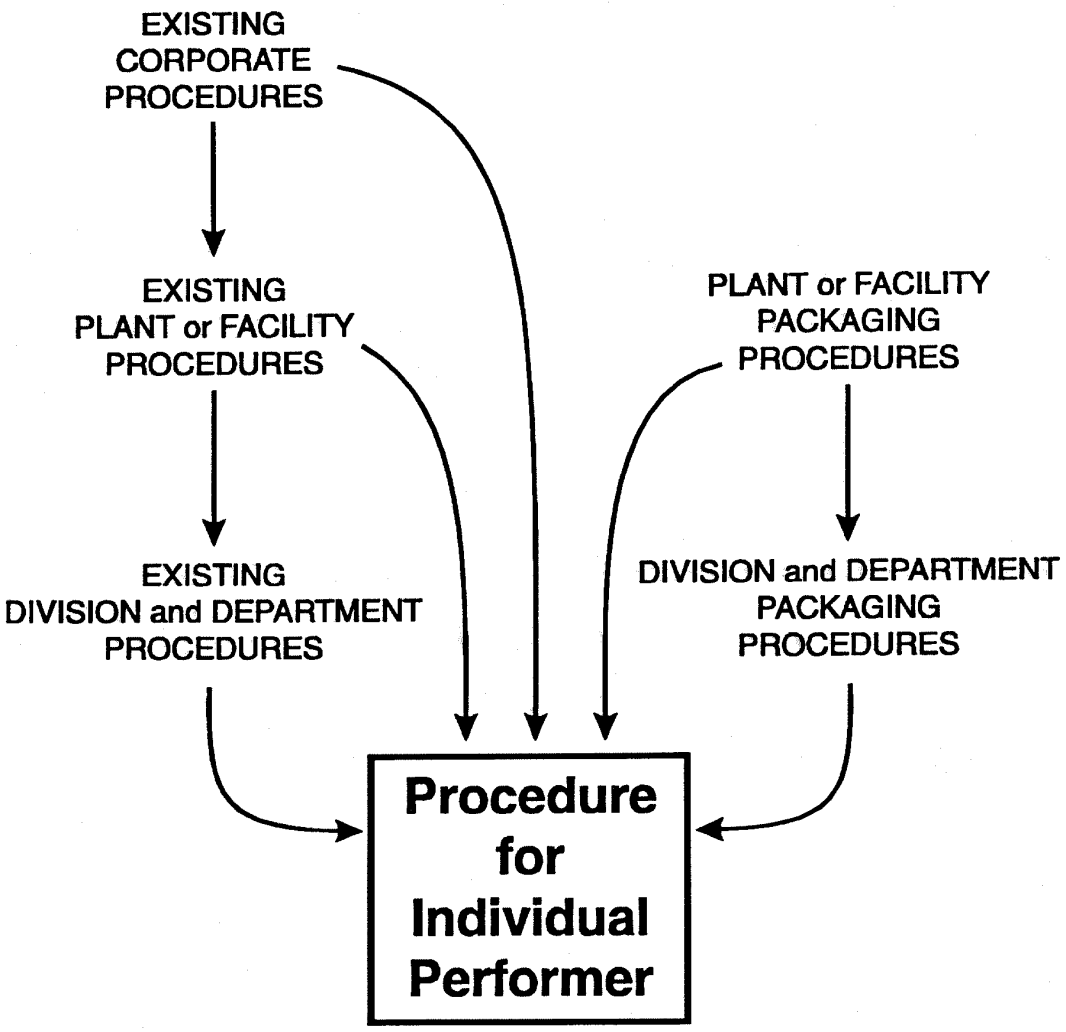

Fig. 9.6. Procedure for individual performer.

9.3.7 Quality Assurance Program Description

The packaging owner's and the user's Packaging Program QA Program Description (QAPD) describes the program for management and operations of the related packaging activities. The QAPD includes:

1. Description of work being controlled
2. Description of the control actions
3. Description of the responsibilities
4. List of implementing procedures and instructions

Based on the results of planning activities presented in earlier parts of Sect. 9.3, the packaging program organization prepares the written description of the work activities and their controls with the identified responsibilities in a QAPD. The list of implementing procedures and/or instructions may be included in an appendix or attachment.

QAPD will include a requirements matrix that allows the packaging user to trace each applicable QA criterion to its applicable implementing procedure/instruction(s). QAPD should also include a matrix for any other QA standard it addresses and should identify the applicable criterion or requirements and the related implementing procedure/instruction(s). This QAPD should contain sufficient information to be used as the SARP Section 9, "QA."

9.4 PACKAGING QUALITY ASSURANCE PROCESS DESCRIPTION

The packaging owner's processes of designing, fabricating, and placing packaging into service can be characterized in the following categories or phases:

The packaging owner designs, fabricates, and places packaging into service.

1. Packaging Design. This phase generally consists of activities from the initial release of the new packaging concept (including the design input) through the design analysis and design reviews, resulting in a preliminary, prototype package.

2. Packaging Development. This phase generally includes the testing and qualification of the prototype design activities. The results of these tests are documented and then used as input to the SARP and subsequent packaging certification.

3. Packaging Production. This phase generally encompasses procurement of materials and/or components, fabrication of the packaging, assembly, testing and inspection activities. This phase leads to the actual production of the packaging ready for use.

4. Packaging Acceptance. This phase includes the packaging owner's inspection and other verification activities that occur prior to accepting the packaging for use. It normally occurs concurrent with the issued-approved distribution of the SARP and DOE-AL issuing of the Off-site Transportation Certificate.

5. Packaging Use. This operational phase generally consists of activities occurring during the actual use of the individual packaging for transport of components or SNM. It includes activities such as maintenance, modifications, and refurbishments after each use.

These phases and the unique QA requirements related to packaging are described in further detail in the following subsections.

9.4.1 Packaging Design

9.4.1.1 Production of test prototype

The usual design controls as specified in DOE Order 5700.6C apply to packaging design. The design control attributes in essentially all of the QA standards are documentation of design input, identification of applicable standards, procedures for the design process, verification by persons other than those who designed the item, and design change control. The design control attributes are essentially all of the QA standards.

9.4.1.2 Selective application (graded approach)

Guidance provided within DOE 5700.6C establishes risk as the fundamental consideration in determining to what extent the QA program should be applied to components and processes. DOE 5700.6C states that risk is a quantitative and/or qualitative expression of possible loss which considers both the probability of event occurrence causing harm or loss and the consequences of that event. The following criteria, should be considered in determining risk: consequences of failure, probability of failure, data generation function, complexity or uniqueness of design or fabrication, special controls,

ability to demonstrate functional compliance, quality history, degree of standardization, impact on the environment, and impact on schedule or cost or both should be considered in determining risk.

Those determining risk must be technically competent in the area being considered, and should ensure that personnel involved in the major risk assessment activity have the needed expertise, experience, competency, and knowledge to perform the risk assessment properly. The resulting risk assessment data should be used to determine the appropriate technical, management, and administrative controls.

10 CFR 71, Subpart H introduces the graded approach consistent with the importance to safety. The graded approach may be readily applied to packaging design. Appendix A of Regulatory Guide 7.10 provides detailed guidance in the application of the graded approach.

The NRC Regulatory Guide 7.10 provides guidance on the graded approach (i.e., quality categories) which is based on determining which components provide a safety function, and how those components are classified: as "critical," "major," or "minor." It can be readily determined which components provide a safety function; however, the next step requires interpretation of the meaning of "critical," "major," and "minor." Since "minor" carries a connotation of essentially "not important to safety," all packaging components with a safety related function can be classified as either "critical", or "major."

This selective application of QA activities can be based on a component's key safety functions. For packaging of radioactive materials, the key safety functions are criticality, containment, shielding, and protection of personnel, the public or the environment. Using this application, "critical," "major," and "minor" can be defined as follows:

1. If there is any degradation of "containment," "shielding," or "protection of personnel, public, or the environment" upon failure of the component, then the component shall be assigned to the "critical" quality category.

2. If there is no degradation of "criticality," "containment," "shielding," or "protection of personnel, public, or the environment" upon failure of the component, but degradation could occur with a concurrent or subsequent independent failure, then the component shall be assigned to the "major" quality category.

3. If there is no degradation of "criticality," "containment," "shielding," or "protection of personnel, public, or the environment" upon failure of the component and a concurrent or subsequent independent failure, then the component shall be assigned to the "minor or not important to safety" quality category.

These definitions minimize the necessity to continually interpret the meanings of "critical, "major," and "minor," Furthermore, the determination can be based on qualitative assessments of the various functions of each component rather than performing quantitative assessments (i.e., probability calculations based on failure modes using statistical inference) for the full spectrum of design basis conditions.

In accordance with DOE Order 5700.6C, quality categories determined for the packaging components will be documented as quality records for packaging development. The performance test in the next section is an overall design verification, even though it is treated as a part of packaging development.

9.4.2 Packaging Development

9.4.2.1 Readiness to proceed with development

A readiness review should be conducted to confirm readiness to proceed with development. This review should confirm completion, acceptability, and verification or independent checking of analysis, design methodology, and the consistency of the design relative to the design input.

9.4.2.2 Production of test prototypes

The production of the test prototype(s) should demonstrate fabrication methodology and provide acceptable packaging for the performance testing. Production controls should ensure and document that the packaging used in the performance testing is, in fact, equivalent to the production packaging.

9.4.2.3 Test controls

Numerous test controls are essential during the performance testing. The testing incorporates several QA principles. Personnel who conduct the tests, calibrate the M&TE, and interpret the test results should be qualified and have documented verification of their qualifications. Control and documentation of the material and instruments is essential in providing a basis for validation of the test results. Calibration of M&TE before and after the test ensures accurate recording of test data prior to proceeding.

9.4.2.4 Evaluation of performance test results

The usual design control requirements for verification and documentation should be utilized for evaluation of test results. Design change controls should be in place and used to incorporate any design changes resulting from the performance evaluation. The test report should be authenticated by both test personnel and design personnel.

9.4.3 Packaging Production

9.4.3.1 Readiness to proceed with production

Prior to initiating production of the packaging, the readiness to produce should be confirmed with a readiness review. This readiness review should evaluate the completeness of the design and the development. The readiness review should ensure any changes resulting from the performance testing have been incorporated into the technical requirements (drawings, specifications, data sheets, etc.) in the procurement package and into the SARP. The technical requirements in the procurement package, whether for in-house fabrication or outside procurement, should be compared to the issued-for-comment SARP to ensure complete agreement.

9.4.3.2 Packaging procurement

Packaging production may be a procured or in-house activity, but the production controls should be similar in either case. Consistent specification of the vendor qualifications, production controls, and quality certification requirements can be enhanced by standardizing the specification. Quality personnel

will work with the design engineers and the procurement personnel to specify production controls using such a form.

9.4.3.3 Specification of selective application

The safety function of the component being produced influences the quality requirements imposed during production. While production controls must be based on each component's safety functions, the following are examples of the supplier controls that could be considered for the three safety functions or activity categories.

1. "Critical" Quality Category

    a. Fully implemented QA programs based on accepted QA standards

    b. Plans for manufacturing, inspection, testing, and packaging and shipping which are reviewed and have comments incorporated prior to release for manufacturing

    c. QA procedures submitted for review and comment prior to release for manufacturing

    d. Audits of supplier QA prior to release for manufacturing

    e. Access to vendor plant during manufacture

    f. Special process specifications and procedures with process qualification guidance

g. First article evaluation when complex items are being procured

h. Identification and control of individual components

i. Nonconformances dispositioned as "accept" or "repair" and submitted for approval

j. Inspections at supplier plants prior to shipment

a. Certification package for each component shipped that includes the following:

- Certification that component meets requirements of technical specifications
- Quantitative data for material certification of source materials
- Test and or inspection reports on each individual component
- Special process inspection and test reports on each individual item

2. "Major" Quality Category

a. Plans for QA, manufacturing, inspection, testing, packaging, and shipping

b. QA program evaluation prior to release for manufacturing

c. Special process specifications/procedures with process qualification guidance

d. Access to vendor plant during manufacture

e. Identification and control of individual components

f. Nonconformances dispositioned as "accept" or "repair" and submitted for approval

g. The right to inspect at the supplier plant prior to shipment

h. Certification package for each component shipped that includes the following:

- Certification that the component meets the requirements in the technical specifications
- Quantitative data for material certification of source materials
- Test and or inspection reports on each individual component

3. "Minor" Quality Category

Many packaging components in this category will be commercially available and should not require additional QA requirements other than standard procurement practices. An exception is when there is evidence of poor quality history, such as with fasteners. In such a case, additional QA requirements are necessary.

9.4.3.4 Packaging acceptance

The production records for each individual packaging type should be reviewed before packaging is placed in service. The reviews are intended to verify conformance to requirements and as-built documentation as a basis for configuration control. This will result in documentation of actual conditions when nonconformance reports have been dispositioned Use-As-Is or Repair.

DOE-AL's review and approval of the SARP and the subsequent issuance of the packaging certificate for use occurs during packaging acceptance. Once the certification process is complete, the packaging is ready for use by the packaging owner or the user.

9.5 PACKAGING USAGE

9.5.1 Timing of the User's Quality Assurance Program

The packaging owner's QA program should be in place before the initiation of design. However, the packaging user's QA program does not need to be in place until the packaging certificate is issued and actual use begins. The packaging user typically packs, unpacks, or services the packaging. However, each packaging user's QA program should begin well in advance to use a process similar to that described in Sect. 9.3.

Each packaging user's QA program should address the commitments in the operating procedures section of the SARP, and the commitments in the QA section of the SARP which apply to the packing, unpacking, or refurbishing activities to be performed.

9.5.2 Extent of the User's Quality Assurance Program

The content of a packaging user's QA program may be limited if the packaging user does not replace parts or otherwise change packaging configuration. When a packaging user only packs and does not change the packaging configuration, then the packaging user's QA program need only include the basic programmatic elements and any achieving elements applicable to the packing, unpacking, and

support activities (e.g., Subpart H programmatic elements 1, 2, 5, 6, 15, 16, 17, and 18, and achieving elements such as 12, 13, 14).

9.5.3 Configuration Management

Each packaging SARP requires that the design configuration of all safety-related features is maintained throughout its life cycle. Each packaging user must notify the packaging owner if any configuration change to a safety-related packaging item or component is contemplated that would affect form, fit, or function. These recommended design changes must be reviewed and approved by the packaging owner for incorporation before the packaging user can make any requested changes.

If a packaging user replaces parts or does work on the packaging that alters the configuration, the packaging user's QA program must control these activities. The level of control depends on the nature of the activity. For example, when a packaging user gets a replacement part from the packaging owner and the packaging owner has already qualified the part in accordance with the packaging owner QA program, the controls may be referenced to the packaging owner program. However, if a packaging user actually procures a replacement part, the controls must be sufficient to ensure that the part meets all of the packaging owner's specific requirements and that the documentation is traceable from the packaging owner's configuration back through the packaging user to the supplier.

Nonconformances and other failures to meet requirements which are discovered during packaging user activities must be coordinated with the packaging owner. Any disposition that introduces a change in the packaging has to be incorporated into the packaging owner's configuration management defining documentation. Furthermore, it is important for the packaging owner to incorporate this information into the data base of problems for quality improvement. The packaging owner requires root causes of

nonconformances or other failures to meet requirements in order to facilitate trending and quality improvement as required by DOE Order 5700.6C.

9.6 CONCLUSIONS

This Design Guide for packaging QA is intended to assist packaging owners and users in development and implementation of an effective QA program consistent for safe off-site transportation. The following subsections summarize the key points essential to a successful and effective program.

This Design Guide provides the overall QA program guidance for ensuring that quality is achieved in the packaging program. The QA activities described are carried out in conjunction with the QA activities identified in this Design Guide and will provide the packaging owner and user with an objective basis for confidence that quality is achieved during the design and use of each packaging.

9.6.1 Implementing Multiple Standards

There are many standards containing requirements that may be applicable, as discussed in Sect. 9.2. In addition to the QA standards, there are other requirements in more general technical requirements documents.

Once the applicable standards and requirements are selected for application, a vital part of the QA program is the documenting of the flowdown of these requirements into implementing policies, procedures, and practices. The method chosen should demonstrate the degree of requirements application and flowdown to the implementing level.

9.6.2 Use of Currently Acceptable Program

Many contractor facilities and organizations have implemented QA programs which typically include acceptable policies, procedures, and practices. This guide allows the packaging QA program to build on these programs or on existing packaging quality programs or plans. It is intended to integrate with ongoing programs. It is not the objective of this guide to ignore acceptable programs; rather, its goal is to assess adequacy and effectiveness, improve, and augment to the extent necessary to meet and respond to applicable standards and requirements.

9.6.3 Selective Application

DOE Order 5700.6C establishes risk as the main consideration when using a graded approach to apply QA. Those determining risks must be technically competent in the area being considered. 10 CFR, Subpart H, presents the graded approach according to safety. This method applies readily to packaging. Regulatory Guide 7.10 presents the graded approach according to safety, after which categories ("critical," "major," and "minor") are used to define a component's risk. As required in DOE Order 5700.6C, the categories will be documented as quality records for packaging development.

9.6.4 Packaging Owner and User Interfaces

The packaging owner and users are the principal participants in a packaging QA program. The cooperative interface between them is the key to the success of a complete, integrated ongoing program that achieves and assures quality packaging. Following are brief discussions of four general areas that require their focused attention.

9.6.4.1 Quality assurance program integration

The packaging owner and each user should understand and interface with each other's QA programs, policies, procedures and practices for packaging. They also must ensure that the program interfaces effectively in procedures and practices.

9.6.4.2 Packaging owner is responsibility for configuration

The packaging owner must establish, maintain, and require the use of procedures and practices that document and control packaging configuration throughout the package's life cycle.

9.6.4.3 Packaging user's procedures

Packaging users must identify any procedures and practices that may alter package configuration. These procedures and practices should ensure that safety related features of the packaging are not altered in violation of the SARP. Packaging users must provide information on configuration changes to the packaging owner as specified in the packaging owner's procedures.

9.6.4.4 Packaging nonconformance and corrective actions systems

Finally, the packaging owner's and user's nonconformance, corrective action, and lessons learned programs must work in concert so that trends and problems are identified, understood and corrected. Lessons learned experience should include not only negative issues, but also positive practices. Lessons learned experience will contribute to the ever improving quality and effectiveness of weapons packaging.

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9.7 REFERENCES

1. U.S. Department of Energy, *Quality Assurance*, DOE Order 5700.6C, Washington, DC.

2. U.S. Department of Transportation, Title 49, Code of Federal Regulations, Title 49, *Transportation*, Parts 171-179, *Hazardous Materials Regulations*, Washington, DC.

3. U.S. Nuclear Regulatory Commission, Code of Federal Regulations, Title 10, *Energy*, Part 71, Subpart H, *Quality Assurance*, Washington, DC.

4. Appendix A, "Quality Principles" from DOE 5700.6C, Personal Communication, Jose Munoz, DOE/AL, September 22, 1993

5. Appendix B, "Quality Principles" from 10 CFR 71, Subpart H, Personal Communication, Jose Munoz, DOE/AL, September 22, 1993

6. ASME NQuality Assurance-1, *Quality Assurance Requirements for Nuclear Facilities*, NQA 1 (1989).

7. U.S. Department of Energy, *Quality Assurance*, DOE Order 5700.6B, Washington, DC.

8. U.S. Department of Energy, *Quality Criteria*, QC-1, Albuquerque Office, (Rev 6, 1992)

9. U.S. Nuclear Regulatory Commission, Regulatory Guide 7.10, *Establishing Quality Assurance Programs for Packaging used in the Transportation of Radioactive Material*, Washington, DC, (Rev. June 1, 1986)

10. U.S. Department of Energy, *Materials Transportation and Traffic Management*, DOE Order 1540.1, Washington, DC

11. U.S. Department of Energy, *Hazardous Material Packaging for Transport - Administrative Procedures*, DOE Order 1540.2, Washington, DC

12. U.S. Nuclear Regulatory Commission, Title 10, *Energy*, CFR, Part 71. *Packaging*, Washington, DC

13. U.S. Department of Energy, *Packaging and Transporting of Nuclear Components, and Special Assemblies*, DOE Order 5610.1, Washington, DC

14. U.S. Department of Energy, *Packaging and Off-Site Transportation of Components and Special Assemblies Associated with the Nuclear Weapons Program*, Draft 10/25/91, DOE Order AL SD 5610.1, Albuquerque, NM

15. DOE Order 5480.3, *Safety Requirements for the Packaging and Transportation of Hazardous Materials, Hazardous Substances, and Hazardous Wastes*

16. International Atomic Energy Agency (IAEA), *Code on the Safety of Nuclear Power Plants, Quality Assurance*, Safety Series No. 50-C-Quality Assurance

17. International Standards Organization, *Model for Quality Assurance in Design/Development, Production, Installation, and Servicing,* ISO 9001

18. U.S. Department of Energy, *Procedures at DOE Nuclear Facilities* DRAFT, DOE Order 5480.PRO, Washington, DC

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APPENDIX A

DOE ORDER 5700.6C

QUALITY PRINCIPLES

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APPENDIX A

DOE ORDER 5700.6C

QUALITY PRINCIPLES

This appendix is a simplified list of the QA principles embodied in DOE 5700.6C. This list is included to enhance understanding. However, when applying this order to a packaging program, one must work from the order and not from this list.

Criterion 1 -- Program

- Shall be developed, implemented, maintained, and written.

- Shall describe organizational structure, functional responsibilities, levels of authority, and interfaces.

- Program shall describe the management system, including planning, scheduling, and cost control considerations.

Criterion 2 -- Personnel Training and Qualification

- Personnel shall be trained and qualified.

- Provide continuing training to ensure job proficiency.

Criterion 3 – Quality Improvement

- Establish and implement processes to detect and prevent quality problems.

- Corrective action shall identify the causes of problems and prevent recurrence.

Criterion 4 -- Documents and Records

- Documents shall be prepared, reviewed (to include validation), approved, issued, used, and revised to prescribed processes.

- Records shall be specified, prepared, reviewed, approved, and maintained.

Criterion 5 -- Work Processes

- Work shall be performed to established technical standards and administrative controls.

- Work shall be performed under controlled conditions using approved instructions, procedures, or other appropriate means.

- Items shall be identified and controlled to ensure their proper use.

- Items shall be maintained to prevent their damage, loss, or deterioration.

- Equipment used for process monitoring or data collection shall be calibrated and maintained.

Criterion 6 – Design

- Items and processes shall be designed using sound engineering/scientific principles and appropriate standards.

- Design work, including changes, shall incorporate applicable requirements and design bases.

- Design interfaces shall be identified and controlled.

- Adequacy of the design products shall be verified and validated. Verification and validation shall be completed before approval and implementation of the design.

Criterion 7 -- Procurement

- Organizations shall ensure procured items and services meet established requirements and perform as specified.

- Suppliers shall be evaluated and selected on the basis of specified criteria.

- Organizations shall ensure that approved suppliers can continue to provide acceptable items and services.

Criterion 8 -- Inspection and Acceptance Testing

- Inspection and acceptance testing of specified items and processes shall be conducted using established acceptance and performance criteria.

- Equipment used for inspections and tests shall be calibrated and maintained.

Criterion 9 -- Management Assessment

- Management at all levels shall periodically asses the integrated QA program and its performance.

- Problems shall be identified and corrected.

Criterion 10 -- Independent Assessment

- Assessment shall be conducted to measure item quality and process effectiveness and to promote improvement.

- Persons conducting independent assessments shall be technically qualified and knowledgeable in the areas assessed.

APPENDIX B

10 CFR 71, SUBPART H

QUALITY PRINCIPLES

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APPENDIX B

10 CFR 71, SUBPART H

QUALITY PRINCIPLES

This appendix is a simplified list of the QA principles embodied in 10 CFR 71, Subpart H. This list is included to enhance understanding. However, when applying this regulation to a packaging program, one must work from the order and not from this list.

71.101 Quality Assurance Requirements

- Has a QA program been established, maintained, and executed?

- Has the applicable criteria been applied in a graded approach?

71.103 Quality Assurance Organization

- Establish and delineate in writing the authority and duties of persons and organizations performing support activities.

- Assure that an appropriate QA program is established and effectively executed.

- Verify through the use of checking, auditing, or inspection.

71.105 Quality Assurance Program

- Document QA program through written procedures or instructions.

- Identify the material and components covered by the QA program, the major organizations participating, and their designated functions.

- Provide indoctrination and training of personnel.

71.107 Package Design Control

- Use applicable regulatory requirements in specs, drawings, procedures, and instructions.

- Establish measures for identifying and controlling design interfaces.

- Establish written procedures among participating design organizations for review, approval, release, distribution, and revision of documents involving design interfaces.

- Check design adequacy through reviews, alternate or simplified calculations, or suitable testing.

- Apply design control measures for criticality, physics, radiation shielding, stress, thermal, hydraulic, and accident analyses; compatibility of materials; accessibility for in service inspection, and repair; features to facilitate decontamination; and delineation of acceptance criteria for inspections tests.

- Subject design changes, including field changes, to design control measures commensurate with those applied to the original design.

71.109 Procurement Document Control

- Establish measures to assure adequate quality is required in the documents for procurement of material, equipment, and services.

71.111 Instructions, Procedures, and Drawings

- Prescribe activities affecting quality be documented instructions, procedures, or drawings.

71.113 Document Control

- Establish measures to control the issuance of documents.

- Measures must assure that documents, including changes, are reviewed for adequacy, approved for release by authorized personnel, and distributed and used at the location where the prescribed activity is performed.

71.115 Control of Purchased Material, Equipment, and Services

- Establish measures to assure that purchased material, equipment, and services conform to the procurement documents.

- Have documentary evidence that material and equipment conform to the procurement specifications prior to installation or use.

- Assess the effectiveness of the control of quality by contractors and subcontractors.

71.117 Identification and control of Materials, Parts, and Components

- Establish measures for the identification and control of materials, parts, and components.

- Maintain identification by heat number, part number, or their appropriate means, either on the item or on records traceable to the item.

- Identification and control must prevent the use of incorrect or defective materials, parts, and components.

71.119 Control of Special Processes

- Establish measures to assure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures.

71.121 Internal Inspection

- Establish and execute a program for inspection of activities affecting quality.

71.123 Test Control

- Establish a test to assure that all testing required to demonstrate package performance, is identified and performed in accordance with written test procedures.

- Document and evaluate the test results to assure that test requirements have been satisfied.

71.125 Control of Measuring and Test Equipment

- Establish measures to assure that tools, gages, instruments, and other measuring and testing devices are properly controlled, calibrated, and adjusted.

71.127 Handling, Storage, and Shipping Control

- Establish documented measures to control the handling, storage, shipping, cleaning, and preservation of materials and equipment, to be used in packaging to prevent damage or deterioration.

71.129 Inspection, Test, and Operating Status

- Establish measures to indicate the status of inspections and test performed (e.g., stamps, tags, labels, routing cards, etc.).

- Measures must identify items having satisfactorily passed required inspections and tests to preclude inadvertent bypassing of any inspections and tests.

- Establish measures to identify the operating status of components of the packaging (e.g., tagging valves and switches to prevent inadvertent operation).

71.131 Nonconforming Materials, Parts, and Components

- Establish measures to control materials, parts, or components which do not conform to requirements, to prevent their inadvertent use or installation.

- Measures must provide written procedures for identification, documentation, segregation, disposition, and notification to affected organizations.

- Nonconforming items must be reviewed and accepted, rejected, repaired, or reworked in accordance with written procedures.

71.133 Corrective Action

- Establish measures to assure that conditions adverse to quality (e.g., deficiencies, deviations, defective material/equipment, and nonconformances) are promptly identified and corrected.

- For significant conditions, the cause of the condition is determined and corrective action taken to preclude repetition.

- The cause of the condition and the corrective action taken must be documented and reported to appropriate levels of management.

71.135 Quality Assurance Records

- Sufficient records must be maintained to describe the activities affecting quality.

- Records must include the instructions, procedures, and drawings required under 71.111.

- Written procedures must be in place which establish a records retention program, consistent with applicable regulations.

- Procedures must designate duration, location, and assigned responsibilities.

71.137 Audits

- Planned and periodic audits must be performed to verify compliance with all aspects of the QA program and to determine the effectiveness of the program.

- Audits must be performed in accordance with written procedures or checkiists by appropriately trained personnel.

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